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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/675,225
Filing Date: September 29, 2003
Appellant(s): MAXWELL ET AL.

Susan L. Wang, Ph.D., Reg. No. 53,742
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/07/2007 appealing from the Office action mailed 09/15/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 5,462,946	Mitchell et al.	10-1995
US 6,426,080 B1	Golz-Berner et al.	7-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-2, 6-10,12-18,20-25 are rejected under 35 U.S.C. 102(b) as being unpatentable by Mitchell et al. (US 5,462,946).

Mitchell teaches pharmaceutical compositions and their methods of use, the compositions contain nitroxide compounds (including TEMPOL) that can be used as radiation protectants for skin, mucositous and hair loss (also known as alopecia), which can be applied as an ointment, lotion or cream (satisfying the claim for a gel or thickened liquid), and intravenously or orally by pill or lozenge. See col 1 lin 10-13, col 2 lin 53-58 and claims 1 and 10. While the patent is silent on specific solvents it is deemed inherent by the examiner that in order to make a topical cream or lotion the active ingredient would have to be dissolved in some type of solvent and the patent describes the compounds having concentrations of from 1-5 mM and the use of acceptable carriers. See col 4 lin 40-42 and lin 47-51. Regarding claims 7 and 21, while Mitchell only discloses treatment of skin conditions, it is inherent that protecting against skin conditions commonly associated with radiotherapy would include group in claims 7 and 21 (discussed as being common skin conditions in appellant's spec [0004]) and since the radioprotective agent is the same in both patents it would protect against all skin conditions the same as applicants claimed invention. Regarding claim 10, the Mitchell patent teaches the exact same amount of active ingredient for topical use as the appellants. See col 5 lin 18-21. Regarding claims 12 and 25, it is deemed inherent by the examiner and a normal part of experimentation by someone skilled in the art to

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adjust the viscosity of a topical gel so that it "will remain in contact with a treated area for a sufficient period of time to allow absorption of a pharmacologically effective amount into said treated area" thus this claim was given no patentable weight by the examiner. Regarding claims 24 and 25, applying the composition topically to prevent harmful effects of radiotherapy is taught by Mitchell (see col 2 lin 53-58) and evaporating solvent after applying topically is inherent since the solvents listed are volatile (methanol) and would eventually evaporate when applied to a persons skin.

Claims 1-17 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (US 5,462,946) in view of Golz-Berner et al. (US 6,426,080 B1 is used as an English equivalent to WO 99/66881).

The Mitchell patent teaches as above.

The Mitchell patent is silent on the exact solvents and polymers used in the topical skin application.

Golz-Berner discloses a cosmetic preparation of active substances to protect the skin (including TEMPOL) in the form of a gel composed of hydrogels (including natural polymers such as hydroxymethylcellulose), solvent (including ethanol) and other ingredients such as carriers (propylene glycol and water are listed). See col 3 lin 23-29 col 6 lin 6-9, col 7 lin 3 and lin 60-62, col 9 lin 13 and lin 37-40.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Mitchell discloses all of the claimed invention by the appellants except the exact solvents and polymers used while Golz-Berner discloses a cosmetic preparation

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of active substances to protect the skin including TEMPOL and discloses the use of solvents, carriers and hydrogels which are the same as the appellant's claimed ingredients (ethanol, propylene glycol, water and natural polymers). One of ordinary skill in the art would have a reasonable expectation of success in combining the references above because they are both related to the same general field of endeavor, namely topical compositions comprised of TEMPOL for protection from harmful free radicals. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

(10) Response to Argument

Claims 1-2, 6-10,12-18,20-25 are rejected under 35 U.S.C. 102(b) as being unpatentable by Mitchell et al. (US 5,462,946).

Appellants assert that Mitchell does not disclose a thickened liquid or a gel formulation and instead teaches the use of ointments, lotions or creams. Appellants further assert that they have clearly distinguished in their specification both the gel and thickened liquid from other formulations such as creams, lotions, shampoos, cream rinses and ointments. Appellants further argue that their claims also require a low-residue formulation which is not taught by Mitchell. Appellants assert that the formulations of Mitchell such as ointments, lotions, rinses and the like are all residue

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formulations which are specifically distinguished from appellant's specification as not being "low-residue". Appellants assert that in order to anticipate claim 24 evaporation of the solvent must take place before the radiotherapy is applied to patient and Mitchell does not disclose the timing of applying the application before the radiotherapy is applied.

The examiner respectfully disagrees with appellants arguments discussed above. Firstly the examiner does not view appellant's claims to a pharmaceutical composition in the form of a low residue gel to be as limiting as appellant's remarks in their appeal brief. From appellant's own specification at paragraphs [0091]-[0097] "a gel relates to a semisolid system of either suspensions made up of small inorganic particles or large organic molecules interpenetrated by a liquid. Generally, if left undisturbed for some time, gels may be in a semisolid or gelatinous state. With some gels, small amounts of water may separate on standing.... Gels can be one-phase or multiple phase systems..... A gel mass consisting of a network of small discrete particles is generally termed a two-phase system while single-phase gels typically consist of organic macromolecules distributed uniformly throughout a liquid in such a manner that no apparent boundaries exist between the dispersed macromolecules and the liquid." The above recitations within the specification do not seem to be particularly limiting as to the final form of appellant's invention. The "gel" described by appellant's is basically a semi-solid form that can have some water and can be one phase or multiple phases. This definition would not seem to preclude a cream or lotion that can also be said to be semi-solid and contain one or more phases. Since Mitchell teaches the same ingredients as the scope of applicants claimed invention the compositions form will be essentially the same. While Mitchell does not

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expressively state the compositions are gels, appellant's specification and claimed invention in its present state is not limiting enough to exclude lotions or creams.

Appellant's have not described or limited their invention in such manner to exclude a composition as in Mitchell which contains all of their claimed ingredients. Regarding the assertions by appellants that low residue precludes Mitchell from anticipating their claimed invention, once again since Mitchell teaches all of appellants claimed ingredients the properties of the composition would be the same. Thus since Mitchell teaches all of appellants claimed invention and appellants have not amended their compositions ingredients such that the composition does not read on Mitchell the limitation is considered met. Also it is of note that "low-residue" is a relative term and as such it is unclear how limiting the recitation is in regards to the amount of residue that can be present for a composition to still read on appellant's claimed invention.

Regarding appellant's assertion that Mitchell does not meet claim 24, the examiner interpreted claim 24 in the broadest reasonable way, the claim only states that the method of treatment comprises applying a sufficient amount of nitroxide radioprotector, evaporating solvent and applying radiotherapy to said patient. The claim only states as currently written that the solvent evaporates, it does not disclose that all of the solvent is evaporated. Indeed any reasonable solvent that would be used as a carrier in a pharmaceutical composition would evaporate almost immediately especially a more volatile carrier such as water or methanol. As far as the time required to evaporate the solvent before applying radiotherapy Mitchell does not disclose this limitation but then neither does appellant, at least in claim 24. The examiner can only search the prior art

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for what is included within a claim limitation, since appellants did not claim the time for the solvent to evaporate the examiner did not search this limitation.

Claims 1-17 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (US 5,462,946) in view of Golz-Berner et al. (US 6,426,080 B1 is used as an English equivalent to WO 99/66881).

As in the arguments summarized above Appellant's assert that neither Mitchell nor Golz-Berner disclose a low-residue formulation. Appellant asserts that Golz-Berner is concerned with preparing cosmetic preparations, which are designed to keep its radical protection potential over a long period of time, which is in contrast to topical formulations that are designed to leave little residue on the skin after a short time period. As an example appellants point out that a significant fraction of phospholipids are present in the composition of Golz-Berner which appellants surmise would not evaporate quickly. Appellants further assert that the examples for creams within Golz-Berner also use glycerine which would further slow the rate of evaporation. Thus appellants surmise one with skill in the art upon combining Mitchell and Golz-Berner would use the disclosed phospholipids and glycerine which would leave a residue and cause topical burning during radiotherapy. Appellants further assert there is no apparent reason to combine the references, other than hindsight reconstruction. Appellants further assert that the two references are not related to the same field of endeavor because Golz-Berner is concerned with the preparation of cosmetic preparations

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containing extracts from plants and insects while Mitchell is concerned with compositions with a very specific use of protecting against ionizing radiation. Thus appellants surmise one of skill in the art would be unlikely to turn to known cosmetic formulations for guidance in producing a very different medicinal formulation to protect from radiation.

The relevance of these assertions is unclear. The arguments above by the examiner for why Mitchell meets appellants claimed low-residue gel or thickened liquid are incorporated herein. Firstly in regards to Golz-Berner being in contrast to appellant's claimed invention because it keeps its radical protection potential over a long period of time. Golz-Berner was used primarily in combination with Mitchell for its disclosure of cosmetic active substances to protect the skin and the use of solvents, carriers and hydrogels, which are the same as appellant's claimed ingredients (ethanol, propylene glycol, water and natural polymers), which Mitchell did not disclose. By combing the two references one skilled in the art could use the active disclosed in Mitchell (TEMPOL) with the solvents, carriers and hydrogels in Golz-Berner which are the same as appellant's claimed invention. Secondly the fact that Golz-Berner discloses glycerine in the examples does not mean that Golz-Berner teaches away from applicants claimed invention because clearly there were several other carriers listed that would be volatile such as ethanol and water. The examples within Golz-Berner were given solely for the purpose of illustration and were not to be construed as being limiting to their invention since many variations are possible without departing from the spirit and scope of the

invention. Also in regards to the use of phospholipids, appellants failed to mention that the amount of phospholipids could be in amounts as low as 0.1%, this is not seen by the examiner as an amount that would leave a sufficient amount of residue of on the skin to be excluded by the relative limitation "low-residue gel". This argument is also not found persuasive because Golz-Berner was used in a 103(a) rejection as a secondary reference primarily for its disclosure of the use of solvents, carriers and hydrogels which are the same as the appellant's claimed ingredients (ethanol, propylene glycol, water and natural polymers), in combination with Mitchell, who does not disclose the mandatory use of phospholipids in the nitroxide protectant composition. The rejection was based on the reasoning that it would have been obvious to one skilled in the art to include and/or modify the solvents and carriers of Golz-Berner with the composition of Mitchell. In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA

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1971). Regarding appellant's assertion that the references are unrelated, the examiner respectfully disagrees, the references are at least broadly related as protective compositions for use against free radicals. It is also noted that the compositions can contain the same active ingredient TEMPOL, thus one of ordinary skill in the art on researching compounds containing TEMPOL could have come across the two references when designing a like composition.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/James W. Rogers/, Ph.D.

Examiner

AU 1618

Conferees:

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

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